DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 11, 2015

Sorin Group Italia S.r.l.
% Barry Sall RAC, FRAPS
Principal Consultant
PAREXEL Consulting, LLC
195 West Street
Waltham, Massachusetts 02451

Re: K150489
Trade/Device Name: EOS PMP, EOS PMP Integrated
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: April 10, 2015
Received: April 13, 2015

Dear Barry Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150489

Device Name
EOS PMP
EOS PMP Integrated

Indications for Use *(Describe)*

EOS PMP Integrated: Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir
The device is intended for use in patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 5 liters /minute. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir with cardiotomy filter is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patient's veins (gravity or vacuum assisted) during normal operation to assure the proper oxygenation capability of the device. The device is intended to be used for 6 hours or less.

Patient population: Paediatric/small adults

EOS PMP: Hollow Fiber Oxygenator
The device is intended for use in patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 5 liters /minute. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The device is intended to be used for 6 hours or less.

Patient population: Paediatric/small adults

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

SUBMITTER:	Sorin Group Italia 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 39 0535 29811 Fax: 39 0535 25229
DATE PREPARED:	May 28, 2015
DEVICE TRADE NAME:	EOS PMP EOS PMP Integrated
COMMON NAME:	Hollow Fiber Oxygenator Hollow Fiber Oxygenator with integrated hardshell venous/cardiotomy reservoir Hardshell Venous/Cardiotomy Reservoir
CLASSIFICATION NAME:	Cardiopulmonary Bypass Oxygenator/ Cardiopulmonary Bypass Heat Exchanger/ Cardiopulmonary Bypass Blood Reservoir/ Cardiopulmonary Bypass Defoamer
CLASSIFICATION CODE:	DTZ
REGULATION NUMBER:	870.4350
UNMODIFIED DEVICE(S):	D905 EOS: hollow fiber oxygenator with integrated hardshell venous/cardiotomy reservoir (K043323)

DEVICE DESCRIPTION:

The EOS PMP is a high efficiency hollow fiber diffusion membrane oxygenator with integrated heat exchanger.

The device provides oxygenation and carbon dioxide removal from patient's blood. The integrated heat exchanger controls blood temperature and allows the use of hypothermia, or aids in the maintenance of normothermia during surgery.

The device can be operated at flow rates up to 5 liters per minute (l/min).

The device can be connected with, but not limited to, the D905 EOS reservoir (K043323) that collects, defoams, and filters patient's blood.

The EOS PMP is a modified version of the currently marketed D905 EOS (K043323).

INDICATION FOR USE:
The intended uses for the device models are:

EOS PMP Integrated: Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir
The device is intended for use in patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 5 liters /minute. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir with cardiotomy filter is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patient's veins (gravity or vacuum assisted) during normal operation to assure the proper oxygenation capability of the device. The device is intended to be used for 6 hours or less.

EOS PMP: Hollow Fiber Oxygenator
The device is intended for use in patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation with a maximum blood flow rate of 5 liters /minute. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The device is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:
The EOS PMP has the same fundamental technological characteristics, principles of operation and control mechanisms as the unmodified device.
The EOS PMP can be operated at a minimum blood flow rate of 0.5 LPM rather than 1 LPM and is provided with a different oxygenating fiber consisting of polymethylpentene (PMP, surface area approx. 1.4 m^2) rather than the polypropylene fiber used for the unmodified device (PP, surface area approx. 1.1 m^2). As a result the static priming volume is ≤200 ml rather than ≤210 ml.

No other changes have been made to the device. The venous/cardiotomy reservoir has not been modified and is not subject of the present 510(k).

Except for the change of the oxygenating fiber, the EOS PMP utilizes the same materials as the unmodified device.

No change to the intended use has been made as a result of these modifications.

The EOS PMP and the D905 EOS unmodified device share the same fundamental technological characteristics except for modifications that do not affect the basic device function. These differences do not raise any new issues of safety and effectiveness.

The devices are substantially equivalent on the basis of operating principles and basic function.

There are no differences in packaging design between modified and unmodified device.

The EOS PMP is ethylene oxide sterilized and has a non-pyrogenic fluid path. It is for single use only.

NON CLINICAL TEST RESULTS:

Applicable tests were conducted in accordance with the requirements of ISO 10993-1.
The current draft Guidance “Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” and its guidelines was also considered limited to external communicating device, circulating blood, limited contact duration.

IN VITRO TEST RESULTS:

In vitro testing was conducted on the oxygenating module that is the only device element subject to modifications with respect to the unmodified device. The tests were performed to demonstrate unmodified device substantial equivalency and compliance to safety and effectiveness requirements.
The tests were conducted in accordance with the relevant requirements of “Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff, November 13, 2000”.
For venous/cardiotomy reservoir, the performance data previously submitted and already cleared are cross referenced.
The following table lists the performance tests conducted. The EOS PMP successfully met all acceptance criteria for each of the following tests.

TEST	TEST CLASSIFICATION	TEST TITLE
1	Functional/Performance	Blood trauma
2	Functional/Performance	Biological activity
3	Functional/Performance	Leaching of coating
4	Functional/Performance	Flaking of coating
5	Functional/Performance	Uniformity of coating
6	Functional/Performance	Blood volume capacity
7	Functional/Performance	Oxygenating performance/blood side pressure drops
8	Functional/Performance	Blood, water, gas pathway integrity
9	Functional/Performance	Plasma leakage

CONCLUSIONS:

The results of in vitro studies demonstrated that the modified oxygenator performs in a manner substantially equivalent to the unmodified oxygenator device with respect to the relevant functional parameters.
Test results of this study demonstrate the EOS PMP is substantially equivalent to the D905 EOS unmodified device with respect to device function.
Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.